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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,847	09/28/2001	Rina Goldshtein	23908-501	5004

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EXAMINER

LEWIS, PATRICK T 7

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,847

Applicant(s)

GOLDSHTEIN, RINA

Examiner

Patrick T. Lewis

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn to a hydrophobic inclusion complex comprising nano-sized water-insoluble lipophilic particles and an amphiphilic polymer or a method for producing said complex, classified in class 530, subclass 300; class 536, subclass 22.1+. Claims 8-18 and 33-49, drawn to a method for forming a hydrophilic inclusion complex comprising forming an emulsion comprising an amphiphilic molecule in an aqueous solvent and lipophilic compounds in a non-aqueous solution, forming nano-sized lipophilic particles in a nano-emulsion, and removing carrier solvent from nano-emulsion, classified in class 530, subclass 300; class 536, subclass 55.3.
 - II. Claims 19-32, drawn to a chemical reactor comprising a first vessel, a second vessel, and a dispersing apparatus, said dispersing apparatus being positioned within said first vessel, said first and second vessels being connected to each other, classified in class 422, subclass 209.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed

can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case it would not have been obvious to one of ordinary skill in the art at the time of the invention to use the instantly claimed apparatus to form hydrophilic inclusion complexes since Kamiwano et al. (US 5,921,478) teaches a chemical reactor comprising a first vessel, a second vessel, and a dispersing apparatus, said dispersing apparatus being positioned within said first vessel, said first and second vessels being connected to each other which may be used as a kneader, a roll mill, a medium-dispersing machine and the like to disperse a solid dispesoid used as a material for coatings, inks, ceramics, cosmetics, foods, and the like, or as homogenizers and the like to emulsify a liquid dispesoid .

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. It would indeed impose an undue burden upon the examiner in charge of this application if the instant restriction and species requirement were not advanced as set forth herein.

In the event applicant elects the invention of Groups I, applicant is required to elect a species in accordance with the provisions set forth below:

Claims 1, 8, 33, and 43 are generic to a plurality of disclosed patentably distinct species wherein:

Species 1: lipophilic compound/particle is **A1)** peptide or polypeptide, **B1)** nucleotide and co-ferments, **C1)** vitamins, antibiotics, and hormones, **D1)** porphyrins, **E1)** metal-complexes, **F1)** purines, or **G1)** pyrimidines.

Species 2: amphiphilic polymer is **A2)** natural polysaccharide, **B2)** polyacrylic acid or its derivatives, **C2)** polyethylene imine or its derivatives, **D2)** polymethacrylic acid or its derivatives, **E2)** polyethylene oxide or its derivatives, **F2)** polyvinyl alcohol or its derivatives, **G2)** polyacetylene derivatives or its derivatives, **H2)** polyisoprene derivatives, or **I2)** polybutadiene derivatives.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for **Species 1** and a single disclosed species for **Species 2**, even though this requirement is traversed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Contacts

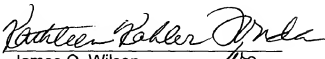
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

KATHLEEN K. FONDA
PRIMARY EXAMINER


James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
March 4, 2003